

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IMPAX LABORATORIES, INC.,	:	Hon. Stanley R. Chesler
	:	Civil Action No. 17-13476
	:	
Plaintiff,	:	
	:	
v.	:	
	:	OPINION
ZYDUS PHARMACEUTICALS	:	
USA, INC. et al.,	:	
	:	
Defendants.	:	
	:	

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for judgment on the pleadings, pursuant to Federal Rule of Civil Procedure 12, by Defendants Zydus Pharmaceuticals USA, Inc. and Cadila Healthcare Limited (collectively, “Zydus.”) As to four of the counterclaims at issue, Plaintiff Impax Laboratories, Inc. (“Impax”) has opposed the motion.¹ For the reasons that follow, the motion will be granted.

This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Impax, which owns patents covering its Rytary® pharmaceutical product, and Zydus, which has filed ANDA No. 210911, seeking to make and sell a generic version of Rytary®. The following facts are undisputed. The Zydus ANDA contains paragraph IV certifications that the proposed product will not infringe any valid claim of six patents listed for Rytary® in the Orange Book. After Zydus sent Impax the required notice letter, Impax filed the instant suit. The Complaint asserts a claim for patent infringement of only one of the six patents in the

¹ Impax does not oppose the motion with respect to counterclaim Count III, involving the ‘427 patent. As to counterclaim Count III, the motion will be granted.

Orange Book, the '608 patent. On April 27, 2018, Zydus filed an Amended Answer to the Complaint asserting, *inter alia*, six counterclaims seeking declaratory judgments of noninfringement for each of the six Rytary® patents listed in the Orange Book. On June 1, 2018, Impax filed an Answer to the counterclaims. As to the '608 patent, Impax denied the counterclaim allegation of noninfringement.

As to the other four patents still at issue on this motion, the counterclaims and Plaintiff's Answer to them follow a pattern. In the counterclaim for declaratory judgment for each of the four patents, Zydus alleged that the manufacture and sale of the proposed product that is "the subject of ANDA No. 210911 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of" the particular patent. (Defs.' Am. Ans. ¶ 50.) In the Answer to the counterclaims, as to each of the four patents, Impax stated: "As of this date, based on the current proposed products that are the subject of ANDA No. 210911, Plaintiff admits the allegations of paragraph __ of the counterclaims." (Pl.'s Counter. Ans. ¶ 50.) This pattern applies to all four of the patents still at issue on this motion: the '474, '998, '283, and '607 patents. The counterclaim Answer is dated June 1, 2018.

Zydus moves for judgment on the pleadings on the ground that, as to the four patents, Plaintiff's statements in the Answer to the counterclaims constitute statements conceding noninfringement. "Under Rule 12(c), judgment will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." Jablonski v. Pan Am. World Airways, Inc., 863 F.2d 289, 290 (3d Cir. 1988). Defendants argue that, because Plaintiff has conceded noninfringement, no factual

issues remain, and they are entitled to declaratory judgments of noninfringement as a matter of law.

In support, Zydus cites Par Pharm., Inc. v. Luitpold Pharm., 2017 U.S. Dist. LEXIS 15050 (D.N.J. Feb. 1, 2017). In Par, defendant Luitpold moved for judgment on the pleadings, seeking judgment on its declaratory judgment counterclaims that the product proposed in its ANDA submissions does not infringe the applicable patents. Id. at *9-*11. In opposition, plaintiff Par argued that the product Luitpold intended to eventually sell, rather than the product specified in the ANDA, would infringe. In a filing, however, Par conceded that the formulations stated in the ANDA did not have the same or equivalent formulation required by the patents-in-suit. Id. at *8.

The Court rejected Par's argument opposing the motion and granted the motion for judgment on the pleadings, citing the Federal Circuit's Glaxo decision. Id. at *15-*16. In Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997), the Federal Circuit differentiated typical patent infringement claims from those brought under 35 U.S.C. § 271(e)(2) as follows: "The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." The Par court rejected Par's argument as speculation: "Par's argument against the entry of judgment for Luitpold at this stage is based entirely on speculation that the FDA will require Luitpold to adjust its product formulation in a way that will infringe the Patents-in-Suit." Id. at *17-*18. Zydus contends that Impax here makes the same argument in opposition that Par did.

Impax attempts to distinguish Par by arguing that it is not here relying on speculation, but on actual concerns the FDA has voiced about the Zydus ANDA product. This argument is unpersuasive. As to the declaratory judgment counterclaims, Impax has speculated that, sometime in the future, and in some unknown way, Zydus will change its ANDA formulation from one that does not infringe to one that does. This is essentially the same argument that Par made, and that that Court rejected. As the Federal Circuit stated in Glaxo, “the question of infringement must focus on what the ANDA applicant will likely market if its application is approved.” 110 F.3d at 1569. Impax has conceded that the product that is the subject of ANDA No. 210911, as of June 1, 2018, does not infringe. That is the product that Zydus will likely market if ANDA No. 210911, as it stood on June 1, 2018, is approved. The argument that Zydus might market something different from what was in its ANDA on June 1, 2018 has no relevance to the question of whether the product that is the subject of ANDA No. 210911, as of June 1, 2018, infringes.

Impax makes two arguments in opposition to the motion: 1) Impax did not make the concessions claimed by Zydus; and 2) recent events, subsequent to the filing of the pleadings, raise factual disputes. As to the first argument, as already stated, the exact statements Impax made all follow this form: “As of this date, based on the current proposed products that are the subject of ANDA No. 210911, Plaintiff admits the allegations of paragraph 50 of the counterclaims.” (Pl.’s Counter. Ans. ¶ 50.) This Court need not closely parse the meaning of these words, because their meaning is clear: Impax conceded that the product that is, as of the date of the document, June 1, 2018, disclosed in ANDA No. 210911, does not infringe the ‘474 patent.

Impax argues that the word choices in the concession statements somehow preclude a grant of judgment on the pleadings, but does not explain why that should be the case. The parties agree that the standard under Third Circuit law requires that the movant clearly establish that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law. For Impax to make headway with this first argument, it must at least raise questions about one of those two elements – material factual disputes, entitlement to judgment as a matter of law –, but Impax has not done so. Impax has pointed to nothing that raises a material factual question: there is no question that Impax filed the counterclaim Answer containing the concession statements. Nor has Impax pointed to anything which challenges the entitlement of Zydus to judgment as a matter of law. All Impax has done here is to say that its statements in the counterclaim Answer say only what they say. On that point, this Court agrees.

The basis for the Court's conclusion that Zydus is entitled to judgment as a matter of law is quite straightforward. Zydus filed four counterclaims for declaratory judgment of noninfringement. Impax answered those four counterclaims by conceding noninfringement. Zydus is therefore entitled to judgment as a matter of law.

As to the second argument, Impax contends that events subsequent to the pleadings raise factual disputes that preclude the entry of judgment as a matter of law. This fails from the start. Impax clearly conceded that the product disclosed in ANDA No. 210911 as of June 1, 2018 did not infringe the patents. No events subsequent to June 1 can affect the state of the facts as of June 1. Impax clearly conceded the relevant facts as of June 1 and, absent fraud or some other extraordinary circumstance not suggested here, that is conclusive. The material facts are undisputed.

As to the four counterclaims for which the motion is opposed, Zydus has shown that it is entitled to judgment as a matter of law, and the motion for judgment on the pleadings will be granted. As to one counterclaim, the motion is unopposed, and the motion will be granted. Judgment will be entered in favor of Defendants on counterclaims Count III, V, VII, IX, and XI, and the appropriate declarations of noninfringement will be issued.

/s Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: November 29, 2018